REMARKS

Claims 1-31, 41 and 42 are pending in this application. Claims 1-3, 5-6, 8-9, 12-13, 15-16, 23-25, and 42 have been canceled. Claim 4 has been amended to an independent claim and to incorporate the species of original claims 7, 10-11, 14, 17-22, and 26. Claims 7, 10-11, 14, 17-22, 26-28, 31, and 41 have been amended to adjust the claim dependencies. Claims 27, 28, 31, and 41 have been amended to add the phrase "or pharmaceutically acceptable salt, hydrate, or solvate thereof". Support for the amendments can be found throughout the specification and original claims. No new matter has been added. After entry of this amendment, claims 4, 7, 10-11, 14, 17-22, 26-31, and 41 will be pending in this application.

The Office has required restriction between two groups:

> Group I, claims 1-31, drawn to a compound of Formula (I) and a method of using a compound of Formula (I); and
>
> Group II, claims 1-27, 41, and 42, drawn to a compound of Formula (I) and a method of producing a pharmaceutical composition.

(Restriction Requirement, page 2). Applicants hereby elect Group II (claims 4, 7, 10-11, 14, 17-22, 26-27, and 41 of the amended claims of this response) **with traverse**. Applicants acknowledge with gratitude the courtesies extended to their representative, Susanne H. Goodson, by Examiner Chung during an April 3, 2008 telephonic interview regarding the restriction requirement.

As a threshold matter, it is clear that this restriction requirement is seriously flawed as there is no line of demarcation between the two Groups. In order to be fully responsive, Applicants have provided an election and traversed the restriction requirement as summarized herein. However, Applicants respectfully urge the Office to address the flaws discussed herein and reissue the restriction requirement (please see the suggested restriction requirement at page 10 of this response).

During the April 3, 2008 interview, Applicants pointed out that there was no line of demarcation between the two Groups. In particular, the two Groups substantially overlap in scope being drawn to identical compounds of Formula (I), except for the compounds of dependent claim 42 which mysteriously appear in Group II but not Group I. Even more

inexplicably, the pharmaceutical compositions of claim 27 appear in both Group I and II, despite this being the basis for the alleged lack of unity of invention. As there is clearly no line of demarcation between the two Groups, Applicants respectfully requested that the restriction requirement be reformulated and reissued. The Examiner, however, declined to reissue the restriction requirement, insisting that the restriction was proper and that, in any case, the Groups were merely "exemplary" (see also, Restriction Requirement, page 3, setting forth "exemplary" groups). The Examiner further suggested that if Applicants did not agree with the "exemplary" restricted Groups, that Applicants reply to the restriction requirement without electing a Group and set forth their own restriction requirement.

These statements clearly contravene proper restriction practice. First, as pointed out by Applicants' representative during the interview, M.P.E.P. § 818.03(b) requires that an election be made in order for a response to be considered responsive. Second, it is clearly improper for the Office to set forth "exemplary" groups as restriction should only be required upon a careful determination that the restricted groups lack unity of invention. 37 C.F.R. § 1.499. It is perplexing how the restricted Groups can lack unity of invention with each other when they are both drawn, in part, to identical compound structures and identical pharmaceutical compositions. As to shifting the burden to Applicants to provide their own restriction, requiring restriction is clearly at the discretion of the Examiner to be exercised only after the application is found to lack unity of invention. 37 C.F.R. § 1.499; M.P.E.P. § 1893.03(d). *See also*, M.P.E.P. § 803.01 (stressing that it is imperative that restriction be carefully administered as it is at the discretion of the Director). Nevertheless, in order to assist the Office in prosecution of this application, Applicants have suggested an alternative restriction requirement at page 10 of this response.

The current restriction is improper. As will be appreciated, the Office is required to "provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. § 121." M.P.E.P. § 814, citing *Geneva Pharmaceuticals. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003). It should be clear that this line of demarcation is non-existent when both Groups constitute, in part, identical subject matter (see claims 1-27 included in both Groups without any

differentiation). The lack of demarcation will potentially deprive Applicants the protection of 35 U.S.C. § 121 for a later-filed divisional application.

Further, the restriction is improper because the two Groups share unity of invention. The Office states that unity is lacking because the inventions of Groups I and II allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1. As will be appreciated, "unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." M.P.E.P. § 1893.03(d). Unity of invention must be determined under the provisions of the PCT in a national stage application filed under 35 U.S.C. § 371. *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F. Supp. 218 (E.D. Va. 1986). The legal standard for determining unity of invention is set forth in Rule 13, which states, in part:

> the requirement of unity of invention ... shall be fulfilled ... when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

P.C.T. Rule 13.2; M.P.E.P. § 1850. The presence of a special technical feature linking the claims thus defines the unity of invention standard.

The Office states that Groups I and II do not relate to a single general inventive concept because:

> under PCT Rule 13.2, they are not one of the combinations as provided in Annex B, Part 1(e), i.e. that of one product and one method of using or making the product. In Group I, the product is a compound of formula (I) and the method of using the compound of formula (I). In Group II, the product is a pharmaceutical composition and the method of making the pharmaceutical composition.

(Restriction Requirement, page 3). Annex B, Part 1(e), in turn, sets forth combinations of certain types of claims that are usually considered to have unity of invention. In particular, the section referred to by the Office permits:

> (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product...

> ...a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

M.P.E.P. § 1850. By citing this section of the M.P.E.P., the Office appears to suggest that the current claims must lack unity of invention, because the current application presents a combination of claims which is more extensive than the combination in section (A) (e.g., compounds, pharmaceutical compositions, methods of using the compounds, and methods of producing pharmaceutical compositions). However, section (A) is merely an example of a permissible combination of claims which may be presented in a single application without the claims lacking unity of invention, rather than a hard line rule for determining unity of invention. A combination of claims which does not fall into this category does not necessarily lack unity of invention. Instead, the restricted groups should be independently evaluated to determine if the inventions lack a special technical feature. *Id.* (stating that more extensive combinations than those in category (A) should be looked at carefully to ensure that the requirements of PCT Rule 13 are satisfied). Hence, Groups I and II should be examined to determine if they share a special technical feature and, therefore, have unity of invention.

The Office suggests that Groups I and II lack unity of invention because they are directed to "two products": a compound of Formula (I) and a pharmaceutical composition thereof. This is puzzling as both Groups, in fact, include compounds of Formula (I) and pharmaceutical compositions thereof. Hence, the Office's reasoning for restriction appears to be without basis.

Further, even if the restriction were reformulated to restrict the pharmaceutical compositions from the compounds, the examples in Chapter 10 of the PCT International Search and Preliminary Examination Guidelines ("Guidelines") suggest that a compound and a pharmaceutical composition will have unity of invention with each other. An examination of Example 10.35 of the Guidelines is particularly illuminating. Example 10.35 concerns two claims as follows:

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

As the claims of Example 10.35 share the special technical feature of a compound A, claims 1 and 2 have unity of invention. The compounds of Formula (I) of claims 1-26 and the pharmaceutical compositions of claim 27 are directly analogous to the claims of Example 10.35 and, therefore, should share unity of invention with each other. Once this conclusion is reached, section (A) cited above should require the Office to allow the claims to be presented in a single application without requiring restriction, as the only other claims pending in the application are a method of using the compounds of Formula (I) and a method of making a pharmaceutical composition which is "specially adapted" for that manufacture.

In summary, it is clear that the restriction requirement is seriously flawed. Applicants respectfully urge the Office to reformulate and reissue the restriction requirement. In order to assist the Office in prosecution of this application, Applicants suggest the following restriction requirement:

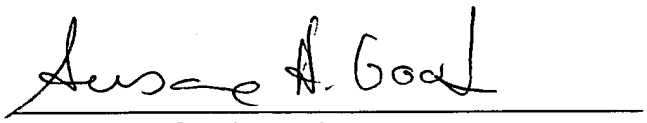
> Group I, claims 4, 7, 10-11, 14, 17-22, 26-27, and 41, drawn to particular species of the invention and pharmaceutical compositions thereof; and
>
> Group II, claims 28-31, drawn to methods of treatment using species of the invention.

The Examiner is urged to contact Applicant's undersigned representative at (302) 778-8411 if there are any questions regarding the suggested restriction requirement or the claimed invention.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to Deposit Account No. 06-1050. Further, if not accompanied by an independent petition, this paper constitutes a Petition for an Extension of Time for an amount of time sufficient to extend the deadline and authorizes the Commissioner to debit the petition fee and any other fees or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 19, 2008



Susanne H. Goodson, Ph.D.
Reg. No. 58,450

Fish & Richardson P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022
Telephone: (302) 652-5070
Facsimile: (877) 769-7945

Enclosure: Three-Month Petition for Extension of Time

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